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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,737	09/29/2003	Lisa Donnelly	22956-0743(MITS021)	1928

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EXAMINER	
COMSTOCK, DAVID C	

ART UNIT	PAPER NUMBER
3733	

NOTIFICATION DATE	DELIVERY MODE
05/06/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/673,737	DONNELLY ET AL.	
	Examiner	Art Unit	
	DAVID COMSTOCK	3733	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 April 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-11*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733

/David Comstock/
Examiner, Art Unit 3733

Continuation of 11. does NOT place the application in condition for allowance because: Examiner maintains the outstanding grounds of rejection for reasons already of record. In addition, in reply to certain assertions made by Applicant in the reply filed 16 April 2010, the following is noted. The rejection is not based on a base reference teaching a material comprising a combination of a bioceramic and a polymer including a polylactic acid and polyglycolic acid (e.g., Wenstrom, Jr. et al. ("Wenstrom") or Agrawal) in view of the bone screw of Beck, Jr. et al. ("Beck"). Rather, the rejection is based on the base reference of Beck who clearly teaches using a bone screw and sets forth the claimed invention except only for the specific material claimed. Wenstrom teaches that implants (for load bearing use in bone tunnels in ACL surgery no less) can be formed of a copolymer of polylactic acid, polyglycolic acid, and a bioceramic, such as tricalcium phosphate, other calcium phosphates, or hydroxyapatite, to provide a material that that allows an implant to biodegrade as bone growth occurs (see, e.g., col. 6, lines 44-50). It is also noted that an interference screw for use in a bone tunnel in ACL surgery is, of course, an implant. While the difference between a bone plug and an interference screw is appreciated, it would have been obvious to a person having ordinary skill in the art to form the screw of Beck of the materials taught by Wenstrom because the device of Beck is a similar implant (also load bearing, also used in a bone tunnel, also used in ACL surgery, etc.). Moreover, the purported evidence against this combination comes from the inventor herself in the declaration filed 01 October 2007. This declaration was not found persuasive for reasons set forth in the rejection mailed 31 December 2007. It is further noted that the declaration is unreliable because it asserts: "the developments I [the inventor] made were substantial in light of the current knowledge within the industry" and "through extensive experimentation a process was formulated that overcame the inherently incompatible properties of the preferred materials to produce a composite of polymer and bioceramic that was effective to promote bone ingrowth." See Declaration, statement 9. The problem is that the prior art references to both Agrawal and Wenstrom already teach a composite of polymer and bioceramic that Applicant alleges she invented. Agrawal even teaches that load bearing implants can comprise a copolymer of polylactic acid, polyglycolic acid and a bioceramic to provide an implant material that is biodegradable but still has sufficient elastic modulus to not break. Therefore, it would not involve hindsight to modify an implant to be formed of implant materials taught in the prior art--especially where the materials are specifically suited for load bearing implants. If Applicant's implant is stronger or more capable of withstanding torque loading, it is because of more care in the process of making it, but cannot be due to Applicant inventing the claimed composite, since the claimed composite was already known in the prior art. In fact, Applicant's declaration admits that the material is stronger due to unclaimed factors: "The preferred materials described and claimed in the above-referenced patent application are notoriously difficult to handle and process even when used separately (i.e., not as composites). The physical and chemical properties of the materials also require careful handling during manufacturing to avoid negative impact on the properties of the composite." See, e.g., Declaration, statement 9, lines 2-5. Applicant also admits that the strength of the material resulted from "careful attention to processing details such as the water content [not claimed] and particle size [not claimed]" (emphasis in brackets by Examiner). See, e.g., Declaration, statement 9, lines 11-12. For all the reasons of record and as further set forth above in response to Applicant's arguments, the outstanding rejection is maintained.